K103202

510(k) SUMMARY

NOV 2 3 2010

SUBMITTER:

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86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

CONTACT PERSON:

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DATE PREPARED: October 29, 2010

DEVICE TRADE NAME: Preassembled Surgical Wash Set

COMMON NAME: Washing Set for Autotransfusion System

CLASSIFICATION NAME: Apparatus, Autotransfusion

UNMODIFIED DEVICE: Preassembled Surgical Wash Set (#K872161)

PREDICATE DEVICE :

Preassembled Surgical Wash Set for Dideco Electa Autotransfusion System (#K020647).

Preassembled Surgical Wash Set for ABMS/Compact Advanced Autotransfusion Equipment (#K982650).

Bowl Set for XTRA Autotransfusion System (#K101586).

DEVICE DESCRIPTION:

The Preassembled Surgical Wash Set is sterile, non-pyrogenic device designed for blood collection from the operating field or from the extracorporeal circuit, washing, concentrating and reinfusion of the blood products to the patient. The Preassembled Surgical Wash Set is composed of a rotary separation chamber (i.e. bowl) and bags connected with the appropriate tubing and connectors to fit the intended autotransfusion equipment.
The device may be offered in different configurations based on the specific autotransfusion machine for which it is designed. The basic components and the intended use remain the same.
The device is a modified version of the unmodified device, Preassembled Surgical Wash Set.

The modifications consist of: the removal of the silicone treatment from the inner surface of the bowl; the removal of "Y" adaptor resulting in minor modifications to the configuration of the circuit; a general updating of the labeling.

The modified device has an unchanged intended use, materials (with the exception of the removal of the silicone treatment from the inner surface of the bowl), sterilization process, operating principles, control mechanisms, and fundamental scientific technology.

INDICATION FOR USE:

The device is intended for use with specific Autotransfusion machines which are identified on the primary label. It contains the basic components necessary to process blood collected during open heart or other surgical procedures for autotransfusion.

TECHNOLOGICAL CHARACTERISTICS:

The modified Preassembled Surgical Wash Set has the same operating principles and control mechanisms when compared to the unmodified device.
With the exception of the removal of the silicone treatment, the modified Preassembled Surgical Wash Set utilizes the same materials. Minor changes have been introduced in the circuit configuration due to the removal of the "Y" adaptor (#K872159) which is an accessory used to connect the wash set to a cardiotomy reservoir.

No change to the intended use has been made as a result of these modifications.

There are no differences in packaging type and material between unmodified and the modified Preassembled Surgical Wash Set.

The Preassembled Surgical Wash Set is ethylene oxide sterilized and has a non-pyrogenic fluid path. It is for single use only.

NON CLINICAL TEST RESULTS:

Applicable tests were carried out in accordance with the requirements of ISO 10993-1:2003 and the FDA May 1st, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of raw materials.

The results of the testing met established specifications.

IN VITRO TEST RESULTS:

In vitro testing was performed in order to provide the data necessary to demonstrate both the substantial equivalence with the unmodified device and also to comply with safety and effectiveness requirements.

The tests were performed according to internal methods developed by the manufacturer.
Since the main modification to the unmodified device is the removal of silicone treatment from the inner surface of the bowl all the tests were performed on sterile wash sets where only the bowl was aged (accelerated aging up to 3 + 1 years). For comparative purpose the modified and unmodified Preassembled Surgical Wash Sets were compared.
The devices were installed on the proper Autotransfusion machine and were tested according to the autotransfusion procedures used by the equipment for blood processing. The results of these tests met established specifications.

CONCLUSIONS:

The modified Preassembled Surgical Wash Set performs in a manner substantially equivalent to the unmodified Preassembled Surgical Wash Set with respect to biocompatibility and the functional parameters. Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.
In conclusion test result of this study suggests the Preassembled Surgical Wash Set is equivalent to the unmodified Preassembled Surgical Wash Set with respect to device function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

PAREXEL Consulting LLC
c/o Mr. Barry S. Sall
Principal Consultant
195 West Street
Waltham, MA 02451

NOV 2 3 2010

Re: K103202
Preassembled Surgical Wash Set
Regulation Number: 21 CFR 870.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II (two)
Product Code: CAC
Dated: October 29, 2010
Received: November 1, 2010

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K103202

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Device Name: Preassembled Surgical Wash Set
Indication for Use:

The Preassembled Surgical Wash Set is intended for use with specific Autotransfusion machines which are identified on the primary label. It contains the basic components necessary to process blood collected during open heart or other surgical procedures for autotransfusion.

Prescription Use___X____
(Part 21CFR 801 Subpart D)

Over-the- Counter Use_____
AND/OR (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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